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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,158	09/29/2006	Hans Jorg Meisel	17346-0033	2935

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SUTHERLAND ASBILL & BRENNAN LLP
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EXAMINER

SCHNEIDER, LYNN SY M

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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08/16/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,158

Applicant(s)

MEISEL, HANS JORG

Examiner

LYNNSY SCHNEIDER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-14,16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-14,16,18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/2011, 7/12/2011</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7, 9, 11-14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (Pat. No. US 6,440,168 B1) in view of Erickson et al. (Pat. No. US 6,368,350 B1).

3. Regarding claims 1-7, and 9, Cauthen discloses a parts assembly 20, 22 (figures 1A-1B) for a prosthesis 10, particularly a cervical spine intervertebral disc prosthesis, comprising two base parts 20, 22, which are coupled to one another in an articulated manner by means of coupling parts 40, 42 (figures 1A, 1B) formed on the base parts 20, 22, wherein the base parts 20, 22 are in each case formed in one piece with an associated coupling part 40, 42, wherein the base parts 20, 22 and their associated coupling parts 40, 42 are made of the same material (col. 5, lines 30-36) wherein one of the coupling parts 42 comprises a sliding surface "hemispherical projection" 48 and the other of the coupling parts 40 comprises a countersliding surface "socket" 46 (figure 2), the sliding surface 48 and the countersliding surface 46 being coated with a Co-Cr alloy coating (col. 5, lines 37-46). An anatomically adapted contact surface 60, 70 (figure 3) is formed on a respective outer side of the two base parts 20, 22. An anti-rotation means 32 (figures 1A-1B, figure 2) is formed on each of the two base parts 20, 22.

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Alternatively, the anti-rotation means can comprises a web arranged on the respective outer side (col. 7, lines 60-64). The two base parts 20, 22 are coupled to one another in an articulated manner by means of a sliding connection (col. 5, line 63-col. 6, line 6).

The sliding connection is embodied by means of the sliding surface 48 and the countersliding surface 46, which is adapted to the sliding surface (col. 5, line 63-col. 6, line 6), wherein the sliding surface is slidably supported on the countersliding surface in the coupled state of the two base parts 20, 22 (figure 2). The sliding surface is formed on a hemispherical protrusion 48 on the coupling part 22 (figure 1A). The two base parts are at least partially coated (col. 5, lines 41-47).

Cauthen discloses the claimed invention except wherein the material of the coupling parts is selected from the following group of materials: polyetherketone (PEK), polyetheretherketone (PEEK), polyacryletherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneetherketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK).

However, Erickson et al. teaches that the coupling parts of an implant can be formed of PEEK for the purpose of providing a non-compressible implant so that the overall height of the implant does not change substantially when subjected to the axial forces of a patient's body weight (col. 5, lines 49-58).

It would have been obvious to one skilled in the art at the time the invention was made for the implant disclosed by Cauthen to be formed of PEEK, as taught by Erickson, for the purpose of providing a non-compressible implant so that the overall

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height of the implant does not change substantially when subjected to the axial forces of a patient's body weight (col. 5, lines 49-58).

4. Regarding claims 11-14, 16, and 18, Cauthen discloses a part for a prosthesis parts assembly (figure 1A), particularly a cervical spine intervertebral disc prosthesis part, comprising a base part 20 and a coupling part 46 formed on the base part 20 for articulated coupling to another base part 22 (figures 1B and 2), wherein the base part 20 and the coupling part 46 are formed in one piece, and made of the same material (col. 5, lines 30-36), wherein the coupling part 46 comprises a sliding surface "socket" that is coated with a Co-Cr alloy coating (col. 5, lines 37-46). An anatomically adapted contact surface 60 on an outer side of the base part 20 is provided (figure 3). An anti-rotation means 32 on the outer side of the base part 20 is provided (figures 2 and 3). Alternatively, the anti-rotation means comprises a web arranged on the respective outer side (col. 7, lines 60-64). The sliding surface "socket" is curved. The base part 20 is at least partially coated (col. 5, lines 41-47).

Cauthen discloses the claimed invention except wherein the material of the coupling parts is selected from the following group of materials: polyetherketone (PEK), polyetheretherketone (PEEK), polyacryletherketone (PAEK), polyetherketoneketone (PEKK), polyetherketoneetherketoneketone (PEKEKK) and polyetherketoneetherketone (PEKEK).

However, Erickson et al. teaches that the coupling parts of an implant can be formed of PEEK for the purpose of providing a non-compressible implant so that the

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overall height of the implant does not change substantially when subjected to the axial forces of a patient's body weight (col. 5, lines 49-58).

It would have been obvious to one skilled in the art at the time the invention was made for the implant disclosed by Cauthen to be formed of PEEK, as taught by Erickson, for the purpose of providing a non-compressible implant so that the overall height of the implant does not change substantially when subjected to the axial forces of a patient's body weight (col. 5, lines 49-58).

5. Claims 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Erickson et al. and further in view of Nishijima et al. (Pat. No. US 5,899,941).

Regarding claims 10 and 19, Cauthen as modified by Erickson et al. discloses the claimed invention except wherein the anatomically adapted contact surfaces have a material coating.

However, Nishijima et al. teaches that the anatomically adapted contact surfaces of an implant can be coated with a hydroxyapatite material, for the purpose of providing the implant with an outer surface which has excellent affinity with a living body (col. 5, lines 32-36).

It would have been obvious to one skilled in the art at the time the invention was made to modify the anatomically adapted contact surfaces of the implant to be coated with a hydroxyapatite material, for the purpose of providing the implant with an outer surface which has excellent affinity with a living body (col. 5, lines 32-36).

Response to Arguments

6. Applicant's arguments with respect to claims 1-7, 9-14, 16, 18, and 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynnsy Schneider whose telephone number is (571)270-7856. The examiner can normally be reached on Monday through Thursday from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Eduardo Robert, at (571) 272-4719***. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./
Examiner, Art Unit 3733

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775